研究ノート

Model of Regulation on Medical Innovation/ Medical Research from the Perspective of Comparative Law*

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1 Introduction

The area of life science is very dynamic and flexible. For example, Aldous Huxley had already such a symbolic novel “Brave New World” in connection with in-vitro-fertilization in 1932, and recently, we have just known a new symbolic invention of “induced pluripotent stem cell (=iPS Cell)” by Prof. Shinya Yamanaka of Kyoto University in Japan in 2007, by which we have had just possibilities to use “regenerative medicine”or “tissue engineering” without breaking human embryos like in case of using “embryonic stem cell(=ES Cell)”. And then many efforts are being made to overcome the risk of cancer which will derive from the technique of iPS Cell.

(Note)

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In the post genome era, it may be disadvantages for mankind that the law too strongly regulates scientific and medical activities in this field because it can obstruct the progress of life science or medicine. Therefore on the one hand, it is true that the freedom of study and research is guaranteed by the Art. 23 of the Constitution in Japan. But on the other hand, we must carefully examine whether this freedom is unlimited or not. Prof. Koichi Bai, who is the founder of medical law in Japan, had already pointed out some important fundamental perspectives on this aspect in 1974;

1) awareness of the limit of legal intervention into natural facts and progresses of natural science,

2) role of law in adjusting conflict between one interest and the other interest, and

3) awareness of positive meaning of legal approach, or guarantee and establishment of fundamental rights.(1)

These perspectives seem to me very useful also today. We must consider the balance between promotion of life science or medical science and protection of human right in this field. Thus we must rethink how we should regulate illegal misconducts in this field. On this point, also Prof. Dr. Albin Eser, who is one of the most famous scholar of medical law in Germany, had expressed similar opinions in 1984, and recently proposes a global theory. In his theory, he insists that we should change our paradigm from "Sektorales Medizinrecht" (Sectoral Medical Law) into "Integratives Medizinrecht" (Integrative Medical Law including bioethics) in 2006.(2) I agree with his opinion.

（1） Koichi Bai, Kagaku to Ho to Seimei to (Science, Law and Life), in Takamine Matsuo (Ed.), Seimeikagaku Noto (in Japanese) (Life Science Note), 1974, Tokyo University Press, p. 197ff. especially pp. 200–201.

In connection with these perspectives, in this paper, I will show a model of regulation on medical innovation/ medical research from the perspective of comparative law.(3)

2 Objects of Regulation

We can classify objects of regulation into three categories. The first is objects to regulate clearly; e. g. crimes, social harmful conducts (trafficking), abuse of eugenics, genetic discrimination, and human cloning (not including therapeutic cloning). We should legally prohibit these conducts due to such harmfulness to our society, and therefore impose criminal sanction on these conducts.

The second is objects to promote; e. g. genome research. Naturally, it needs due process in going on the study plan, but it is not necessary to regulate it legally.

The third is objects to be permitted with certain conditions; e. g.

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(2) Albin Eser, Perspektiven des Medizin (straf) rechts. In: Wolfgang Frisch (ed.), Gegenwartsfragen des Medizinstrafrechts (in German), 2006, pp. 9-31. This article is translated into Japanese by Katsunori Kai/ Yoshinori Fukuyama, in Katsunori Kai (Ed.), Posuto Genomu Shakai to Ijiho (in Japanese) (Post-Genome Society and Medical Law), 2009, Shinzansha, p. 31ff., and Kenji Ueda/Kazushige Asada (Ed.), Ijikeiho kara Tougoutekiijiho e (in Japanese) (Von Medizinstrafrecht zu integrativem Medizinrecht), 2011, Seibudo, p. 265ff.

(3) See in detail Katsunori Kai, Seimeikagaku to Hoteki Ruru (Life Science and Legal Rule), in Waichiro Iwashi/Toru Masui/ Yasuko Shirai/ Tomoko Hasegawa/ Katsunori Kai, Kogi: Seimeikagaku to Ho (in Japanese) (Lecture: Life Science and Law), 2008, Shogakusha, p. 191ff.; Katsunori Kai, Hikakuhoteki Kanten kara mita Sentaniryo/Igakukenkyu no Kisei no Arikata (Model of Regulation to Medical Innovation and Medical Researchfrom the Viewpoint ofComparative Law), Katsunori Kai (Ed.), supra,note (3), Post-Genome Society and Medical Law, p. 190ff.

therapeutic cloning, use of ES-cell, stem cell and iPS-cell. As we cannot concretely foresee any risks and results, we should watch these researches with certain conditions. We can hope that they may bring about possibilities to cure some curable diseases in near future. In my opinion, it is appropriate that the UK Report of House of Lord (2002) has already declared this direction. Also in Japan recently, this direction has been officially confirmed. Naturally, also it needs due process in going on the study plan, but it is not necessary to regulate it legally.

3　Grounds of Regulation

What can we think about the ground of regulation? In my opinion, firstly, it should be based on "Human Dignity" (Menschenwürde in German), which derives from German philosopher Immanuel Kant. "Human Dignity" is "Sein mit Menschen-Dasein"and should be behind human being, human tissues, corpse, and human embryo.

However the problem of ownership or property on his/her body conflicts with "Human Dignity". Generally speaking, libertalianism is affirmative to ownership or property on his/her body.(4) But it seems strange to me to grasp human body as property. We should consider human body rather in connection with "Human Dignity".

Then what should we think about criminal regulation? In my opinion, criminal regulation should be the last measure (ultima ratio). There are some fundamental principles in applying criminal law. Incidentally,

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(4) So also Jean- Pierre Baud, L'affaire de la main volée. Une histoire juridique du corps, Paris, Édition du Seuil, 1993 (This book is translated into Japanese by Prof. Hiroyoshi Nogami, 2004, Hosei University Press). But he is not a libertarian.

Japanese criminal law has been strongly influenced from German criminal law.

The first principle is "Tatprinzip" (Conduct-principle in English). According to this principle, we cannot punish a conduct without certifying an external harmful conduct. It includes causation. In Anglo-American jurisdiction, it is concerned with actus reus.

The second principle is "Nulla poena sine lege, nullum crimen sine lege" (No penalty without law, no crime without law). According to this principle, we cannot punish a conduct without a clear provision of law.

The third principle is "Schuldprinzip "(Nulla poena sine culpa ; No penalty without culpability). According to this principle, we cannot punish a conduct without intention or negligence, and criminal responsibility). In Anglo-American jurisdiction, it is concerned with mens rea.

These three principles should be considerated also in the field of medical or life science. At least, we should use criminal sanction in such cases where people feel or have vague and slight misgivings alone in this field.

4 Model of Regulation

Then what should we think about model of regulation? We can classify it into three categories. The first is the hard law style like in Germany. The German "Embryonen Schutzgesetz" (Protection of Embryo Act) 1990) is typical of it because it is a special criminal law. I think, however, that German legal system is not suitable for regulation to medical and scientific field because it is too hard to keep up flexibly with the trend of life science. Indeed in Germany, "Gesetz zur Sicher-

stellung des Embryonenschutzes im Zusammenhang mit Einfur und Verwendung menschlicher embryonaler Stammzellen ＝Stammzell-gesetz—StZG) has been enacted in 2002 (revised in 2008), and by this law, they have been able to use human stem cell for research in Germany. However it seems strange to me that they can use only stem cell which is imported from foreign countries.

The second is the soft law style like in Japan. We have many official guidelines in this field in Japan; for example, Ethics-Guideline for Human-Genome/ Gene Analysis Research (2001, revised 2004 by Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour and Welfare; Ministry of Economy, Trade and Industry), and the Guideline for the Protect of Personal Information for Business Operations Handling Personal Genetic Information (2004; Ministry of Economy, Trade and Industry). The latter is the guideline for buisiness (except use for research), which includes 1) informed consent by documents, 2) genetic counseling, 3) setting up committee, 4) specifying strictly the aim of use, 5) prohibition of getting sensitive information, 6) risk management including anonymity of materials, 7) general prohibition of providing it to the third party, 8) withdrawal of consent, 9) setting up the window for consultations.

However, these guidelines have no legal sanctions, therefore they cannot ensure more effectiveness to exclude remarkable abuses. As they are so-called a kind of "patch work", we cannot understand the fundamental viewpoint. Thus this model is not enough suitable in this field although they are flexible.

The third is the mixed style of the hard and soft law like in UK and Australia etc.. The Human Fertilisation and Embryology Act 1990(= HFEA 1990) and the Human Tissue Act 2004 in UK are typical of it,

and furthermore they are supplemented by some guidelines. According to this model, we can normally correspond with various new medical and scientific technologies and problems.

Thus as a result of comparative study, in Japan, we should aim at this mixed type between hard law and soft law. And yet, we should consider "the Legal Doctrine of Medical Due Process"[(5)]. This is a legal theory which I have insisted for a long time. According to this theory, as a rule, medical innovation/medical research without due process is unlawful. Medical Due Process contains (1) informed consent, (2) balancing between risks and benefits, (3) due review by appropriate ethical committee, and (4) compensation to human subjects system because we cannot foresee concrete risks. Furthermore (5) it contains some exceptional legal sanctions against extreme abuses. Due to this doctrine, we can build a bridge between law, bioethics and medical and scientific research and practice. I think that we can realize it by enacting the Fundamental Law of Bioethics in Japan.

5 Conclusion

Nowadays we are faceed with some concrete problems in this field. For example, problems of genetic information are very important. Recently, the "Genetic Information Nondiscrimination Act" of 2008 (=GINA) has been enacted in USA. It contains the prohibition of genetic information discrimination in health, insurance and employment. And in Switzerland, "Budesgesetz über Genetische Untersuchung beim Menschen" has been enacted in 2004 (2007 enforcement). Also it contains very

(5) See Katsunori Kai, Hikensha Hogo to Keiho (in Japanese) (Protection of Human Subjects and Criminal Law), 2005, Seibudo, Tokyo, p. 7f. and 30ff.

important and very stimulating provisions in Art. 1, 2, 4, 5, 6 etc.. In the Netherlands, "Wet op de medische keuningen" has been already enacted in 1997, which contains a very important provision of Art. 3. Also in Austria, "Gentechnik-Gesetz" has been already enacted in 1994, which contains a very important provision of Art. 67.

To the contrary, in Germany, a suggestion of legislation concerning protection of genetic information was made by Deutscher Bundes Referat in 2002[6], but such a legislation has not been easily realized. However in 2009, the new Act "Gesetz über genetische Untersuchung beim Menschen (Gendiagnostikgesetz)" has been concluded[7]. In Australia, there are only Guidelines on it[8].

Nowadays we should trans-nationally consider the problems of genetic information because the biobank system has become more and more important in the world[9]. The first thing we should have to do is to make the Fundamental Law of Bioethics in Japan in harmonization with foreign countries. We are now preparing this draft with Prof. Ryuichi Ida (Kyoto University[10]). Concerning to important points in

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（6） Deutscher Bundes Referat Öffentlichkeit (Hrsg.), Enquete-Kommission. Recht und Ethik der Modernen Medizin. Schlussbericht (in German), 2002. This book is translated into Japanese by Prof. Jun Matsuda (Superviser), 2004, Chisen Shokan.

（7） See Katsunori Kai, "Gesetz über genetische Untersuchung beim Menschen (Gendiagnostikgesetz)" in Germany, in Medical Law Vol. 25 (2010), p. 197ff.

（8） Don Chalmers, The Governance of Biobanks and Databases for Research－Towards an International Consensus on Ethical Principles, Taiwan Journal of Law and Technology Policy, Vol. 4 No. 1 (2007), p. 5ff.

（9） To legal system of biobank in detail, see Jasper A. Bouvenberg, Property Rights in Blood, Genes and Data, the Netherlands, 2006.

(10) See Ryuichi Ida, Seimeirinri to Ho : Wagakui ni okeru Seimeirinrikihonho no Teigen (in Japanese) (Bioethics and Law in Post-Genome Society : A Proposal of the Fundamental Law of Bioethics in Japan), in Kai (Ed.), supra,

bioethics, we should make a fundamental legal system. The Fundamental Law of Bioethics will be in the center of bioethics. Thus I think it is better that the model of regulation on medical innovation/ medical research should be the mixed type of hard law and soft law, that is to say, four steps which consist of public guideline (=soft law), civil regulation, administrative regulation, and lastly criminal regulation (= hard law).

On this model of regulation, I try to approach to issues on neuroscience[11], nanotechnology and robotics from now on.

note (3), Post-Genome Society and Medical Law, p. 211ff.

(11) To issues of neuroscience, see Katsunori Kai, Neurolaw in Japan, in Tade Mattias Spranger (Ed.), International Neurolaw －A Comparative Analysis, 2011, Springer Verlag, Heidelberg (in printing).